FDA Executive Summary

Prepared for the
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Orthopaedic and Rehabilitation Devices Panel

Classification of Spinal Sphere Devices

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1. Introduction

Per Section 513(b) of the Food, Drug, and Cosmetic Act (the Act), the Food and Drug Administration (FDA) is convening the Orthopaedic and Rehabilitation Devices Advisory Panel (the Panel) for the purpose of securing recommendations regarding the classification of spinal sphere devices, a pre-amendments device which remains unclassified. Specifically, the FDA will ask the Panel to provide recommendations regarding the regulatory classification of spinal sphere devices. The Panel will also be asked to discuss whether this device type fits the statutory definition for a Class III device.

FDA is holding this panel meeting to obtain input on the risks to health and benefits of spinal sphere devices. The Panel will discuss whether spinal sphere devices should be classified into Class III (subject to Premarket Approval), Class II (subject to General and Special Controls) or Class I (subject only to General Controls). If the Panel believes that classification into Class I or II is appropriate for spinal sphere devices, the Panel will also be asked to discuss appropriate controls that would be necessary to mitigate the risks to health.

1.1. Current Regulatory Pathways

The FDA determined that spinal sphere devices for use in intervertebral body fusion procedures were marketed in the US before passage of the Medical Device Amendments on May 28, 1976 (i.e., pre-amendments devices). Because these pre-amendments devices have not been formally classified, the FDA reviews these devices via the premarket notification (510(k)) pathway until the classification process is completed. To date, the FDA has cleared six (6) spinal sphere devices from four (4) manufacturers. Spinal spheres intended for use as non-fusion devices, however, are currently regulated as devices first introduced after the 1976 Amendments (i.e., post-amendments devices) and as such are automatically regulated as Class III and subject to premarket approval (PMA) requirements. The sole focus of this Panel is on the currently unclassified use of these devices to support an intervertebral fusion.

1.2. Device Description

These devices are solid spheres manufactured from metallic (e.g., cobalt-chromium-molybdenum (CoCrMo)) or polymeric (e.g., polyetheretherketone (PEEK)) materials. They are intended to be inserted into the intervertebral disc space following a discectomy in order to maintain disc space height, and provide postoperative stabilization to the affected spinal segment during fusion procedures.

2. Regulatory History

The first clearance of a spinal sphere device via the 510(k) process was based on evidence that a similar device (Harmon Spinal Spheres, otherwise referred to as Interbody Vitallium Spheres, manufactured by the Austenal Company) was in interstate commerce, and labeled for a specific intended use prior to passage of the Medical Device Amendments on May 28, 1976. Importantly, the evidence supporting that this device type was marketed pre-amendments only supported use of this device in intervertebral body fusion procedures. As

such, the first 510(k)-cleared device was determined to be substantially equivalent to the pre-amendments Harmon Spinal Spheres, but with limitations that clearly state that the device is not intended for use in motion-sparing, non-fusion procedures. Since this initial clearance, there have been five (5) subsequent clearances for spinal sphere devices (or modifications to previously cleared spinal sphere devices) via the 510(k) process. Please refer to Table 1 below for a listing of the manufacturers, device names, and associated 510(k) submission numbers for cleared spinal sphere devices:

Table 1: 510(k) clearances for spinal sphere devices

Manufacturer	Device Name	510(k) Number
Medtronic Sofamor Danek	Satellite Spinal System	K051320
Medtronic Sofamor Danek	Modification to Satellite Spinal System	K060415
Biomet Spine	Spinal Stabilizing Sphere System	K063139
Interbody Innovations, LLP	Spinal Spheres	K062992
Interbody Innovations, LLP	PEEK Spinal Spheres	K073105
Life Spine	Spinal Sphere System	K073274

3. Indications for Use

The indications for use (IFU) statement identifies the condition and patient population for which a device should be appropriately used. Representative indications for use for spinal sphere devices cleared in the 510(k)s noted in Table 1 are as follows:

> [This device] is intended to be inserted between the vertebral bodies into the disc space from L3 to S1 to provide stabilization and to help promote intervertebral body fusion. This internal fixation device is intended for, and designed solely for holding bone parts in alignment while they heal. [This device] is intended to be used with bone graft.

4. Clinical Background

This section summarizes the history of intervertebral body fusion procedures, along with specific use of spinal sphere devices in conjunction with these procedures.

4.1. Intervertebral Body Fusion

4.1.1. Intervertebral Body Fusion Devices ("interbody cages")

Intervertebral Body Fusion Devices (i.e., "interbody cages") are used to treat degenerative disc disease and spinal instability. (Stauffer & Coventry, 1972; Ray, 1997; Kuslich, Ulstrom, Griffith, Ahern, & Dowdle, 1998; Mcafee, 1999) They can be inserted using either anterior or posterior approaches to the spine and act by distracting collapsed disc spaces thus returning them to normal height. This, in turn, restores tension to the annulus and spinal ligaments, widens stenotic neural foramina to improve nerve root impingement, and can also place other implants under compression. (Chen et al., 1995) They also have been shown to stabilize motion

segments and are thereby used to facilitate fusion in degenerative spinal conditions. (Fraser, 1995) Over the years, interbody fusion devices have gained traction as a means to support the anterior column of the spine during the process of fusion.

Interbody fusion cages have been used to treat conditions that result in degenerative collapse of intervertebral discs. (Mcafee, 1999) The rates of fusion after anterior interbody arthrodesis have improved from only 66% reported in the 1970's to two year rates of 91% -96% with current interbody fusion devices. (Stauffer & Coventry, 1972; U.S.Food and Drug Administration, 1996; Ray, 1997; Yuan, Kuslich, Dowdle, Ulstrom, & Griffith, 1997; Kuslich et al., 1998)

The history of intervertebral fusion devices dates back to the 1950s, when Dr. Cloward pioneered the original techniques for posterior lumbar interbody fusion (PLIF) across an intervertebral disc space. (Cloward, 1953) At that time, interbody bone grafts were not popular for several reasons, one of which was the lack of efficacious spinal fixation devices to allow for segmental stability while the bone graft consolidated with the host vertebral elements. This has changed over the last two decades with the advent of posterior instrumented fixation (pedicle screws, rods, hooks, and wiring techniques).

Current interbody cages were developed in the 1980s with the design of the Bagby basket (Bagby, 1988), a perforated cylinder initially developed to fuse cervical spines of thoroughbred horses. This design was adapted for the human lumbar spine, which resulted in the first intervertebral body fusion device called the BAK (Spine-Tech, Inc., Minneapolis, MN), a hollow, fenestrated, titanium cylinder meant to be filled with autograft to promote osseous integration. In September 1996, the BAK device was approved by the FDA for use in the open anterior lumbar interbody fusion (ALIF) and posterior lumbar interbody fusion (PLIF) procedures. (U.S.Food and Drug Administration, 1996) In July of 1997, the FDA approved the BAK device for laparoscopic ALIF. There are a myriad of other interbody fusion devices that have been developed since the approval of the BAK device. Further modifications to interbody cages include the shape of implants (i.e., rectangular or trapezoidal shape to normalize sagittal alignment of the treated segment) or the use of different materials (polyetheretherketone (PEEK), titanium alloys, porous tantalum, carbon-fiber reinforced PEEK). These devices generally possess different features to engage with vertebral endplates, allowing them to resist migration and subsidence, and features that allow for the packing of graft material, facilitating bone growth into and through the device. Interbody cages for use with bone grafting material were reclassified and are currently classified as Class II under 21 CFR 888.3080. (U.S.Food and Drug Administration, 2007b) FDA downclassified these devices and established special controls (U.S.Food and Drug Administration, 2007a) based on data obtained through appropriately controlled randomized clinical trials and presented in premarket approval applications for these devices. However, intervertebral body fusion devices that include any therapeutic biologic (e.g., bone morphogenic protein) remain classified as Class III devices.

4.1.2. Spinal Sphere Devices

Currently, spinal sphere devices are cleared in the US as devices intended for use in spinal arthrodesis procedures. The FDA granted the first clearance through the 510(k) process based on documentation that demonstrated that these devices for use in fusion procedures were in commercial distribution prior to passage of the Medical Device Amendments on May 28, 1976. Clinical evidence regarding this use, however, remains limited. A publication by McKenzie notes that "Interbody Vitallium spheres were used successfully as early as 1957 by Paul Harmon in place of a fibular cylinder as an aid to stabilizing the intervertebral disc space and augmenting interbody fusion." (McKenzie, 1995) However, the authors do not report data assessing the effectiveness of these devices for this intended use.

The more commonly discussed use of this device is in motion-preserving, disc arthroplasty procedures, as reported through experience outside the US. Ulf Fernström began implanting stainless steel ball bearings into the center of evacuated discs and termed this lumbar disc arthroplasty in the 1960s. (Fernström, 1966) However, the use of this device as a non-fusion implant is outside the scope of this panel discussion. Spinal sphere devices for use in non-fusion procedures represent indications first introduced post-amendments in the US. As a result, FDA regulates spinal sphere devices with this intended use as a class III device, subject to premarket approval (PMA) requirements.

4.2. Current Standard of Care

The success and widespread use of intervertebral body fusion devices ("interbody cages") have rendered spinal sphere devices intended for use in fusion procedures obsolete. Interbody cages possess several features, as discussed above in Section 4.1.1., which likely contribute to their clinical success. Biomechanically, interbody devices are intended to stabilize the disc space and maintain its height while facilitating fusion development across the interbody disc space. Additionally, these devices share load across the anterior column of the spine, through which approximately 80% of axial loading is transmitted. (Cloward, 1953) Interbody fusion procedures also allow for restoration of disc height, sagittal balance, and lumbar lordosis. (Mummaneni, Haid, & Rodts, 2004) Additionally, fenestrations allow for bone to grow through the device, and endplate features engage with vertebral endplates to resist migration. Taken together, these features support the design benefits of these devices in facilitating fusion across the disc space.

Clinical experience with interbody cages has highlighted the success of these devices. Several studies demonstrate that interbody devices promote a rigid fusion mass that is effective structurally at limiting spinal motion (Kuslich, Ahern, & Dowdle, 1996; Oxland, Kuslich, Kohrs, & Bagby, 1996; Brodke, Dick, Kunz, McCabe, & Zdeblick, 1997). Accordingly, fusion rates with interbody cages used for the treatment of degenerative disc disease, spondylolisthesis, and segmental instability have been reported to be as high as 74%-94%. (Cole, McCall, Schmidt, & Dailey, 2009) The restoration of disc height, as well as the fact that interbody cages help maintain lumbar lordosis and sagittal balance of

the spine, are considered likely reasons as to why clinical outcomes with interbody fusion have been favorable. (Cloward, 1985; Hutter, 1985) Moreover, circumferential spinal fusion with an interbody graft and screw-rod construct has been advocated to decrease pseudoarthrosis rates following treatment of degenerative disease in the lumbosacral spine. (Enker & Steffee, 1994; Gertzbein, Hollopeter, & Hall, 1998; Slosar et al., 2000; Mummaneni et al., 2004; Ames et al., 2005)

5. Literature Review on Spinal Sphere Devices

FDA has conducted a literature review in an effort to gather any published information regarding safety and effectiveness of spinal sphere devices for use in fusion procedures.

5.1. Methods

FDA conducted a literature search to identify any relevant references published up to and including August 15, 2013. We searched two electronic databases (MEDLINE and Embase) using two sets of search terms:

(1) [(spine OR spinal OR intervertebral OR interbody OR vertebral OR vertebrae OR lumbar OR disc OR discs) AND (sphere OR spheres OR spherical OR ball OR balls OR Fernstrom OR Harmon) AND (arthrodesis OR fusion OR "interbody fixation" OR "intervertebral body fixation")]

(2) [(Fernstrom OR Harmon OR "interbody vitallium") AND (sphere OR spheres OR spherical OR ball OR balls)].

The searches were limited to publications in English. After results from each set of search terms were combined and duplicate references were removed, this search yielded a total of 93 results. Following a review of the titles and abstracts, 43 articles were excluded as they were not relevant to spine applications, and an additional 35 articles pertained to spine applications but were irrelevant to the topic at hand (e.g., investigations of other device types, such as arthroplasty devices, pedicle screw systems, etc.). FDA reviewed the remaining 15 articles in greater detail.

5.2. Results

Of the 15 articles FDA reviewed, only four (4) discussed studies related to spinal sphere devices. (Reitz & Joubert, 1964; Fernström, 1966; Rundell, Isaza, & Kurtz, 2011; Siemionow, Hu, & Lieberman, 2012) Through review of citations within these publications, an additional, non-indexed reference (McKenzie, 1995) was found and included in this review.

Importantly, none of the resulting articles specifically investigated use of this device for fusion procedures, but rather for use as an arthroplasty device. A brief discussion of the identified articles has still been included below, however, for completeness.

In the original paper by Fernström, results from patients implanted with stainless steel balls in the lumbar region (n=105) are presented as compared to a control group (n=100) in which the disc space was only evacuated. Follow-up time for the

investigational group was reported to be six (6) months to two and a half (2.5) years, compared to a follow-up of five (5) to eight (8) years for the control group. Subjects were classified in two groups: those with herniated disc and those with "painful disc." Following implantation of the device, low back pain occurred in 12% of investigational subjects initially presenting with a herniated disc, as compared to 60% in the control group with the same diagnosis. For patients initially presenting with painful disc, low back pain occurred in 40% of investigational subjects and 88% of control subjects. Fernström only reports a few isolated incidents of complications – one case in which the device displaced into the spinal canal, and one case of temporary paresis of the peroneus.

Reitz and Joubert discuss five (5) case reports of patients who received spherical prostheses in the cervical spine for the treatment of severe neck pain and headaches. The authors report patient satisfaction and no noted adverse events. The length of follow up, though not always reported, ranges from 48 hours to 6 months postoperatively. The authors state "to date (10 June 1964) we have performed a total of 75 cervical disc arthroplasties with the spherical prosthesis, on 32 patients. We have also implanted the same prosthesis in 19 lumbar discs in 12 patients, for discogenic backache and sciatica." However, the authors do not report additional data regarding these procedures in this publication.

McKenzie reported data from 103 patients implanted with stainless steel balls, 67 of whom were followed for 10-20 years. Subjects were categorized by having either one or more disc protrusions with associated sciatica, neurological deficit and positive correlation with myelography, or "degenerative disc disease or post-discectomy states with associated facet arthritis or instability." Outcomes were based on a disability and outcome assessment, comprised of several components (employment status, Visual Analog Scale (VAS) score, activity level, rest required, sexual activity, and mental outlook). In addition, physical assessments (including posture, range of motion, ambulatory ability, muscle strength, reflexes, and sensory and stress testing) were conducted and included in the patient's overall assessment. Same-level reoperations (including decompression (n=7), decompression and fusion (n=3) and fusion (n=3)) were performed in 17 patients; 11 patients underwent subsequent adjacent-level surgeries; and discitis was reported in four (4) patients. In one patient, the prosthesis was removed and segment fused. Patients with disc herniations demonstrated more "excellent" or "good" results than those with degenerative conditions. Approximately 25% of the study population was reported as having fair or poor results.

Siemionow et al. reports on four (4) patients that required revision surgery at the author's institution following a prior implantation of a cobalt-chrome spinal sphere device. All patients presented with mechanical and/or radicular pain resulting from subsidence and/or migration of the device. Although the authors acknowledge that "according to the FDA label, the device was intended to be used with bone graft, bone substitute, or other osteobiologic," there is no indication that the patients described in this study underwent fusion procedures in conjunction with the implantation of the

spinal sphere device. The authors identify that all four patients demonstrated signs of sphere subsidence based on radiographic assessments. In three of four patients, the sphere was removed and a fusion subsequently performed using femoral ring allograft and facet screw fixation. In one patient, the sphere was not removed secondary to extensive subsidence into both the cranial and caudal vertebrae, which required *in situ* posterior fixation and a posterolateral arthrodesis. All four patients reported improvements following their revision surgeries.

The publication by Rundell et al. is a biomechanical study utilizing Finite Element Analysis that assesses range of motion and facet contact forces resulting from varying degrees of subsidence of these devices. Additionally, the authors reported on the effect of device material (CoCr or PEEK) on resultant strains within the vertebral bodies. As such, we could not obtain information regarding safety or effectiveness of these devices based on clinical practice.

In a few of the aforementioned publications, the authors reference the use of these devices in fusion procedures; however, these references do not appear to be corroborated by valid scientific evidence. McKenzie states "Interbody Vitallium Spheres were used successfully as early as 1957 by Paul Harmon in place of a fibular cylinder as an aid to stabilizing the intervertebral disc space and augmenting interbody fusion". However, upon review of the associated reference (an article captured as a result in the literature search that was conducted), no such reference to use of a sphere was evident in the cited publication. Similarly, Reitz and Joubert state, "Harmon was the first to replace lumbar intervertebral discs with a spherical prosthesis in 1957, but he abandoned arthroplasty in favour of interbody fusion by the anterior route." However, the authors reference personal communication, not published literature, to support this.

5.3. Overview of the Published Literature

Based on a review of the published literature, we could not identify any reports describing spinal sphere devices for use in intervertebral body fusion procedures. Consequently, there is no information characterizing the safety and effectiveness of spinal sphere devices when used for intervertebral body fusion procedures.

6. Risks to Health Identified Using "Manufacturer and User Facility Device Experience" (MAUDE) Database

6.1. Overview of MAUDE Database

The MAUDE database is maintained by the Office of Surveillance and Biometrics at FDA. This database contains adverse events and reportable product problems with medical devices. The database was fully implemented in August 1996, and contains individual adverse event reports submitted by manufacturers, user facilities, importers, and voluntary reporters. Medical device manufacturers are required to report known adverse events as part of the general controls that most medical devices are subject to; patients and consumers are also encouraged to voluntarily report adverse events.

One does need to note the limitations to MDR reporting, including the fact that not all events are captured since this is a voluntary reporting system. In addition, confirming whether a device actually caused a specific event can be difficult based solely on information provided in a given report.

6.2. MAUDE Search Results: Spinal Sphere Devices

The FDA conducted queries of the MAUDE database on July 2, 2013 to identify adverse events related to use of spinal spheres. Search results were restricted by an end date up to and including June 30, 2013, and utilized the parameters of device product code, manufacturer name, brand name, and catalog number. The queries resulted in the identification of 21 unique MDRs on spinal sphere devices. All were related to the Medtronic Satellite Spinal System. Eighteen (18) MDRs were reported as injuries and three (3) as malfunctions. Please refer to Appendix A for a complete listing of the reported MDRs.

Figure 1 displays the date, by year, when the MDRs were received by the FDA. The majority of reports were received on the Satellite System within several years after clearance (first 510(k) cleared in 2005 for the CoCrMo version, second 510(k) cleared in 2007 for the PEEK version).

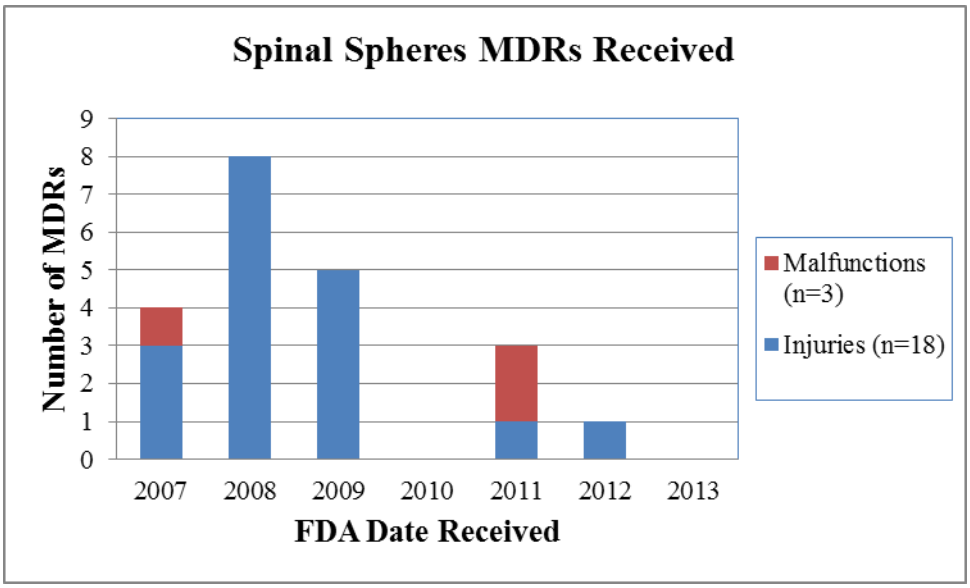

Figure 1: Year MDR received by FDA

The reported adverse events fall primarily into the following categories (please note that multiple adverse events may be related to a single MDR):

- Removal/revision (n=16)
- Pain (n=10)
- Neurological impairment (n=6)
- Subsidence (n=3)
- Migration (n=2)
- Implant breakage during insertion (n=2)

The locations of pain events were stated in four reports: three in the back, and one in the leg. Two additional reports described chronic pain that was unrelieved since surgery.

Further details on the adverse events of neurological impairment were provided in four MDRs: one difficulty walking, one numbness, one loss of sensation, and one paralysis below the waist.

One migration event specified the device migrated posteriorly.

Other events, such as non-fusion, loss of bowel and bladder control, renal issues, trauma, leg swelling, and difficulty sleeping, were also reported as isolated occurrences.

Of the 21 reports, seven (7) contained both the date of implantation and the date of event, allowing the time to adverse event occurrence to be calculated. Four (4) additional reports contained a device removal date, which was used in lieu of the event date. Two (2) reports described the time to event within their event texts; these

were combined with the calculated dates to create Figure 2. The majority of these events occurred within the first year after implantation.

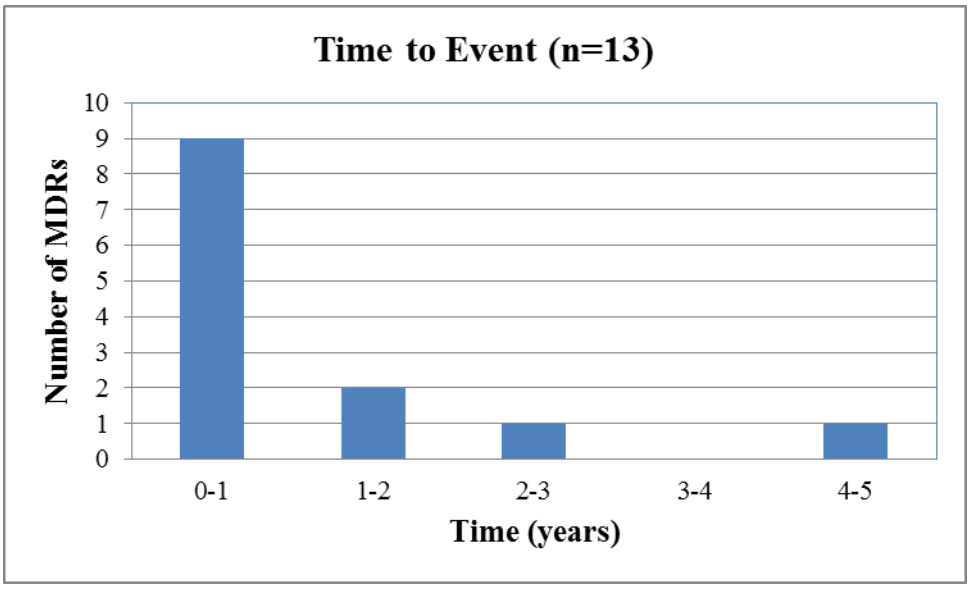

Figure 2: Time from implantation to adverse event occurrence or removal

7. Summary

In light of the information available, the Panel will be asked to comment on whether spinal sphere devices meet the statutory definition associated with a Class III device designation, that is:

- insufficient information exists to determine that general and special controls are sufficient to provide reasonable assurance of its safety and effectiveness, and

- the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury

as opposed to Class II, in which:

- general and special controls are sufficient to provide reasonable assurance of safety and effectiveness.

FDA proposes that spinal sphere devices meet the statutory definition of a Class III device because insufficient information exists to determine that general and special controls are sufficient to provide reasonable assurance of their safety and effectiveness. Additionally, spinal sphere devices present a potential unreasonable risk of illness or injury based on the limited clinical information that has been obtained.

If the Panel does not agree that spinal sphere devices meet the statutory definition of a Class III device, the Panel will be asked for input regarding whether the available scientific evidence supports a Class II determination with special controls, including which special controls could be established to mitigate the known risks to health associated with these

devices. If the Panel supports classification into Class II, the Panel will further be asked to provide reasons for not recommending classification of the device into Class III.

For the purposes of classification, FDA considers the following items, among other relevant factors, as outlined in 21 CFR 860.7(b):

1. The persons for whose use the device is represented or intended;

2. The conditions of use for the device, including conditions of use prescribed, recommended, or suggested in the labeling or advertising of the device, and other intended conditions of use;

3. The probable benefit to health from the use of the device weighed against any probable injury or illness from such use; and

4. The reliability of the device.

Part (g)(1) of this regulation further states that it "is the responsibility of each manufacturer and importer of a device to assure that adequate, valid scientific evidence exists, and to furnish such evidence to the Food and Drug Administration to provide reasonable assurance that the device is safe and effective for its intended uses and conditions of use. The failure of a manufacturer or importer of a device to present to the Food and Drug Administration adequate, valid scientific evidence showing that there is reasonable assurance of the safety and effectiveness of the device, if regulated by general controls alone, or by general controls and performance standards, may support a determination that the device be classified into Class III."

7.1. Reasonable Assurance of Safety

According to 21 CFR 860.7(d)(1), "there is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use."

FDA has identified potential risks to health associated with spinal sphere devices, based on the currently reported adverse events. These include the following:

- Removal/revision
- Pain
- Neurological impairment

The identified risks could result from the reported device-related adverse events including implant breakage during insertion, device migration and/or subsidence.

However, given the limited reported clinical use of these devices for use in fusion procedures, this list may not be exhaustive.

The FDA will ask the Panel to comment on the risks to health identified and whether there are additional risks that should be considered for spinal sphere devices or if any of the identified risks should be removed. Additionally, the FDA will ask the Panel whether the evidence demonstrates a reasonable assurance of safety for the indications for use described above.

7.2. Reasonable Assurance of Effectiveness

According to 21 CFR 860.7(e)(1), "there is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results."

Based on the information we could collect, the FDA is unaware of any documented assessment of the effectiveness of spinal sphere devices for facilitating fusion.

The FDA will ask the Panel whether there is a reasonable assurance of effectiveness for spinal spheres for the indications for use described above.

7.3. Overview of Proposed Classification

As noted above, a device will be considered Class III if:

- insufficient information exists to determine that general and special controls are sufficient to provide reasonable assurance of its safety and effectiveness, and

- the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury.

The literature search performed did not identify any documented evidence of effectiveness. A number of risks to health have been identified based on adverse event reports received by FDA, but not all such risks may be known. Given the limited available information for these devices, FDA does not believe that special controls can be established to mitigate the known risks to health associated with these devices. Therefore, FDA believes that insufficient information exists to determine that general and special controls are sufficient to provide reasonable assurance of the safety and effectiveness of spinal sphere devices.

In addition, FDA believes the spinal sphere devices present a potential unreasonable risk of illness or injury. Although limited information was available, based on the literature search conducted and the evidence obtained from review of the MAUDE database, FDA has identified several documented risks to health, such as need for a secondary procedure for removal or revision, neurological impairment, and pain. Contrary to the identified risks, we were not able to obtain information regarding

successful use of spinal sphere devices for use in intervertebral body fusion procedures. Therefore, FDA believes that the risk of injury is unreasonable given the lack of probable benefit.

Based on the safety and effectiveness information gathered by the FDA, we recommend that spinal sphere devices indicated for use in intervertebral body fusion procedures be regulated as Class III devices.

888.XXXX Spinal Sphere Device

(a) Identification. A spinal sphere device is an implanted, solid, spherical device manufactured from metallic or polymeric materials. The device is inserted into the intervertebral body space of the lumbar spine (L3-S1), and is intended to provide stabilization and to help promote intervertebral body fusion. The device is intended to be used with bone graft.

(b) Classification. Class III (premarket approval).

Based on the available scientific evidence, the FDA will ask the Panel for their recommendation on the appropriate classification of spinal sphere devices for use in intervertebral body fusion procedures.

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Appendix A: Public MAUDE Information on Spinal Sphere Device Medical Device Reports (MDRs)

Report number	Event type	Date FDA received	Event description
1030489-2007-00336	INJURY	11/6/2007	"Date of implant: 2007, it was reported that a patient underwent revision surgery to remove the sphere implant at the l4-5 level and revise to a [TLIF] surgical procedure, approximately 1 month [postoperatively]. According to the surgeon, the 'sphere migrated posterior'. No other patient complications were reported."
1030489-2007-00337	INJURY	11/6/2007	"Date of implant: 2007. It was reported that a [patient] underwent a surgical procedure with a sphere implantation. Approximately 10 months [postoperatively], [patient] complains of chronic pain that has been unrelieved since the surgery. Positive discogram reportedly revealed the upper level symptomatic. Patient underwent a revision surgery to remove the implant and revise to a 2 level [TLIF]. No other [patient] complications were reported."
1030489-2007-00338	INJURY	11/6/2007	"Date of implant: 2007. It was reported that a [patient] underwent a surgical procedure with implantation of a sphere device. At an unknown time [postoperatively], [patient] sustained a traumatic fall on some ice. Xrays reportedly revealed that the implant had migrated posteriorly. Patient underwent revision surgery to remove the implant, [approximately] 1 1/2 months [postoperatively]. No other patient complications were reported."
1030489-2007-00354	MALFUNCTION	11/19/2007	"Date of implant: 2007. It was reported that a patient underwent a surgical procedure with implantation of a sphere device at l5-s1. Patient complains of chronic pain unrelieved after surgery. Positive discogram indicates that patient is symptomatic at an adjacent level. Approximately 6 months [postoperatively], patient underwent revision surgery to remove the sphere device l5-s1 and an [ALIF] at l4-s1 was performed. No patient complications were reported."
1030489-2008-00039	INJURY	1/30/2008	"It was reported that the patient underwent a spinal procedure using interbody device at l4-l5 in 2007. The patient had pain [postoperatively]. It was also found that the device subsided into the endplates. The revision surgery was performed approximately five months [postoperatively] to remove the device."

Report number	Event type	Date FDA received	Event description
1030489-2008-00101	INJURY	2/25/2008	"It was reported that the patient underwent a spinal procedure using the [PEEK] device at l4-l5. The device migrated [postoperatively]. The revision surgery was performed to remove and replace the device."
1030489-2008-00143	INJURY	3/20/2008	"It was reported that a sphere implant was explanted at unknown time [postoperatively] due to recurrent back pain. The surgeon performed an interbody fusion at the revision surgery."
1030489-2008-00254	INJURY	6/4/2008	"It was reported by a non-medical professional that the [patient] underwent a three-level [TLIF] at l3-s1 using three 16mm spherical implants. At an unknown time [postoperatively], the [patient] is reported to have developed 'paralysis below the waist, has been unable to walk or stand on her own, has lost bowel and bladder control, and suffers from severe and permanent neurologic impairment.' [N]o medical reports have been submitted to [M]edtronic that verify these claims. Additionally, no medical evidence linking the implantation of the spherical implants and the [patient]'s reported symptoms has been provided to [M]edtronic."
1030489-2008-00578	INJURY	10/16/2008	"It was reported that the interbody device was explanted approximately one year and nine months [postoperatively], due to [postoperative] pain. No other patient complications were reported."
1030489-2008-00579	INJURY	10/16/2008	"It was reported that the interbody device was explanted due to [postoperative] pain. It was also found that the device was subsided. The implant level was at l5-s1. No other patient complications were reported."
1030489-2008-00580	INJURY	10/16/2008	"It was reported that the interbody device was explanted approximately 11 months [postoperatively] due to [postoperative] pain. The implant level was at l5-s1. No other patient complications were reported."
1030489-2008-00657	INJURY	12/4/2008	"It was reported by a patient that he had undergone a spinal procedure and was implanted an interbody device in 2007. The patient stated that he had the multiple [postoperative] complications such as renal issues, leg swelling, and severe leg pain after the procedure. The device was removed approximately four month [postoperatively] in three months later."

Report number	Event type	Date FDA received	Event description
1030489-2009-00077	INJURY	1/22/2009	"It was reported by a non medical professional that the patient underwent a fusion procedure at l5-s1 in 2005. The surgeon performed a lumbar laminectomy with medical facetectomies and foraminotomies, for complete decompression of the dural and neural elements and transforaminal interbody fusion. An interbody fusion stabilization device was used at l5-s1. At an unknown time [postoperatively], the patient experienced severe back pain and other symptoms. In early 2007, the surgeon performed an additional operation on the patient at l5-s1 to install pedicle screw instrumentation. After this second surgery, the patient continues to have severe symptoms, including loss of sensation, difficulty in walking, and difficulty sleeping."
1030489-2009-00125	INJURY	2/6/2009	"It was reported by a non-medical professional that the patient underwent a surgical procedure in 2007 where an interbody stabilization device was implanted. At unknown points in time after the index procedure, the patient underwent four subsequent exploratory surgical procedures."
1030489-2009-00200[1]	INJURY	2/26/2009	"The revision surgery was done on (b)(6) 2007. It was reported by a non-medical professional that the patient underwent a lumbar stabilization procedure in 2006 where an interbody stabilization device was implanted. The patient underwent a surgical revision to remove the device in 2007 reportedly, due to problems resulting from the initial surgery and the device."
1030489-2009-00207	INJURY	2/26/2009	"It was reported that a revision surgery was performed to remove an implant, and replace with other hardware."
1030489-2009-00216	INJURY	2/27/2009	"It was reported that an implanted sphere devices was explanted."
1030489-2011-00492[2]	MALFUNCTION	5/5/2011	"It was reported that during an unspecified spinal procedure, the implant broke and then detached from the inserter during insertion. The implant was broken into pieces with first hammering during implantation. Another implant was used and no patient complications were reported."

Report number	Event type	Date FDA received	Event description
1030489-2011-01297[3]	INJURY	10/7/2011	"Patient medical records state that the patient diagnosed with l4-5 herniated disc, foraminal stenosis, and left l5 radiculopathy underwent a procedure for left l4-5 microdiscectomy, foraminotomy, and posterior lumbar intervertebral nucleoplasty. [Postoperatively] the patient did well and low back pain decreased, but later developed numbness in the left leg and right foot. An [MRI] showed no evidence of canal or foraminal impingement at l4-5 or the previously fused l5-s1 level. Physical examination was positive for sensory impairment of the left lateral leg and foot and distal right foot bottom. C[T] and myelogram showed no fusion occurring at l4-5 and an uncertain discrepancy in the density of subarachnoid contrast above the l4-5 disc and below l4-5. Approximately 5 months [postoperatively] the patient underwent a second procedure for l4-5 decompression laminectomy and partial l3 laminectomy, followed by posterior lumbar interbody fusion at l4-5 and posterior segmental instrumentation at l4-5. During surgery, it became evident that the posterior elements at l5 had fractured, and the spinous process, as well as the majority of the, lamina bilaterally, were being held by only ligamentous support. Dorsal elements of l5 were removed. Durotomy revealed a constrictive mass that was causing the myelographic block on previous myelogram. Dissection freed all of the nerve roots and [EMG] activity significantly improved. [Postoperatively] the patient symptoms improved, but later low back pain increased with tingling in the legs. The patient underwent a third procedure for removal of the initially implanted interbody device and for [ALIF] with [PEEK] implant. The patient then underwent a fourth procedure for implant of spinal stimulator."
1030489-2011-01633[4]	MALFUNCTION	12/22/2011	"It was reported that a patient underwent an unknown spinal procedure. During the procedure, the implant broke upon insertion. No patient complications were reported."

Report number	Event type	Date FDA received	Event description
1030489-2012-00075	INJURY	1/23/2012	"A [CT] and myelogram done on (b)(6) 2011 showed a failed interbody fusion at l4-5, and narrowing of the l5-s1 disc. It was reported by the patient's attorney that the patient was pre-operatively experiencing recurring lower back pain and pain-producing degenerative changes. The patient underwent posterior spinal surgery in which a spherical interbody device was implanted at the l4-5 level. Reportedly the patient developed neurological injuries [postoperatively] and later underwent another procedure for removal of the device. The patient currently receives pain management treatment."

[1-4]Contained manufacturer narratives with relevant information. See below.

For 17 MDRs, the manufacturer narratives indicated the devices were not returned and the cause of the event could not be determined. In the table above, the report numbers with superscripts contained manufacturer narratives which presented additional information. They are shown here:

[1]"Imaging studies were provided for review. Pre-op lumbar views and [MRI] axials appear normal. [Postoperative] films show interbody device at l5-s1. 4 weeks [postoperative] shows subsidence into l5. Final films show the level revised with interbody [PEEK] spacer, graft and unilateral pedicle screws on the right at l5-s1. Screws are noted to extend beyond the vertebral body anteriorly."

[2]"(b)(4). This part is not approved for use in the [U]nited [S]tates; however a like device, procode [NVR] was cleared in the [U]nited [S]tates. This part is not approved for use in the [U]nited [S]tates; however a like device, 510k # k060415 was cleared in the [U]nited [S]tates. A chip of [PEEK] has been broken off the sphere at the level of the attachment to the implant inserter. The breakage occurred at the end of the threaded hole portion and at the bottom of the lateral handling hole. The chip presents cylindrical marks around the threaded hole corresponding to the contact with the implant inserter. The chip presents also a crack starting from the threaded hole through the handling hole and the outside surface of the sphere. The sphere presents a shaving at the level of the breakage on the outer sphere surface. This shaving is opposite to the handling hole. The last thread of the threaded hole has been shorn off and perpendicular to the shaving. The part returned was found broken at the level of the attachment with the implant inserter. No pre-existing defect was found at the level of the breakage. The observations of the chip and the broken section of the sphere (shaving and shear thread) suggest that the breakage is consistent with an over-loading of the part and the origin of the over-loading can be attributed to the application of a lateral load on the implant inserter during the implantation of the sphere. This lateral load could be linked to a misalignment of the inserter with intervertebral disc space during implantation."

[3]"(b)(4). The device or applicable imaging studies have not been returned to [M]edtronic for evaluation. Unable to determine cause of the reported event.
Patient x-rays were received for review. Multiple studies spanning 2006-2010 show interbody fusion at l5-s1 with degenerative disc at l4. Spherical implant placed at l4-5 and eventual pedicle screws at l4-5. Sagittal views show apparent mass in canal from l4-5 to mid-sacrum which is not seen on axial views. Final x-rays show removal of spherical device with new device paced at l4-5."

[4]"A review of the device history records for this device did not reveal any non-conformances to specification or deviations in procedure which might contribute to the reported event.
(b)(4). Analysis of the returned device showed it to be broken at the level of the attachment with the implant inserter. No pre-existing defect was found at the level of the breakage. The observations of the chip and the broken section of the sphere suggest that the breakage is consistent with an overloading of the part and the origin of the over-loading can be attributed to the application of a lateral load on the implant inserter during the implantation of the sphere. This lateral load could be linked to a misalignment of the inserter with intervertebral disc space during implantation. A review of the device history records for this device did not reveal any non-conformances to specification or deviations in procedure which might contribute to the reported event."